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EXAMINER	
GANGLE, BRIAN J	

ART UNIT	PAPER NUMBER
1645	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

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ADVISORY ACTION

The amendment filed on 11/14/2011, under 37 CFR 1.116, in reply to the final rejection, has been considered and is hereby entered.

Claim 11 is amended. Claims 1-13, 15-16, and 19-23 are pending. Claims 1-10, 12-13, 15-16, and 19-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made without traverse in the reply filed on 1/17/2008.

Claims 11 and 21-23 are currently under examination.

Claim Rejections Withdrawn

The rejection of claims 11 and 21-23 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is withdrawn in light of applicant's amendment thereto.

Claim Rejections Maintained

35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The rejection of claims 11 and 21-23 under 35 U.S.C. 103(a) as being unpatentable over Brassart *et al.* (US Patent Application Publication 2002/0127211, 2002) in view of Birch *et al.* (Am. J. Clin. Nutr., 75:570-580, 2002), is maintained for the reasons set forth in the previous office action.

The instant claims are drawn to methods for inducing a pattern of gut barrier maturation in an infant similar to that observed with breast-feeding, comprising administering to the infant a nutritional composition comprising arachidonic acid (ARA) and/or docosahexanoic acid (DHA), a non-digestible oligosaccharide comprising a milk-derived oligosaccharide and at least one organism selected from the group consisting of *Bifidobacterium* CNCM I-2168, *Bifidobacterium* CNCM I-2169, *Bifidobacterium* CNCM I-2170, *Lactobacillus johnsonii* CNCM I-1225, *Lactobacillus paracasei* CNCM I-2116, *Bifidobacterium lactis* ATCC 27536, and *Bifidobacterium longum* BB536.

Brassart *et al.* disclose methods where by a nutritional composition comprising *Lactobacillus* CNCM I-1225, milk (of various animal and plant types), and various oligosaccharides such as fructo-oligosaccharides is administered (see paragraphs 0022, 0030-0031 and 0039). The composition can be in the form of an infant formula or fermented milk (see paragraph 0044). As the nutritional composition is in the form of infant formula, it is clearly intended to be administered to infants (see claim 7).

Brassart *et al.* differs from the instant invention in that they do not disclose the inclusion of ARA or DHA in the nutritional composition.

Birch *et al.* discuss the benefits of supplementing infant formula with DHA and ARA. Birch *et al.* showed that higher plasma concentrations of DHA and ARA led to better visual acuity and stereoacuity (see abstract). They also showed that DHA and ARA supplementation of infant formula is well tolerated and beneficial to the maturation of the visual cortex in term infants (see final paragraph, page 579).

It would have been obvious to one of ordinary skill in the art, at the time of invention, to add DHA and/or ARA to the infant formula of Brassart *et al.* because such supplementation is beneficial to the maturation of the visual cortex in term infants.

One would have had a reasonable expectation of success because Birch *et al.* demonstrated a benefit of supplementation of infant formula and there is no reason that one of ordinary skill in the art would expect the infant formulas disclosed in Brassart *et al.* to alter the results found by Birch *et al.*

Applicant argues:

1. That Brassart and Birch do not disclose or suggest a nutritional composition comprising non-digestible oligosaccharides comprising a milk-derived oligosaccharide as required by claim 11.

2. That Brassart and Birch do not disclose or suggest a lipid selected from arachiconic acid and docosahexanoic acid, a non-digestible oligosaccharide comprising a milk-derived oligosaccharide and at least one of the recited microorganisms in a single nutritional composition as required by claim 11.

3. That Brassart and Birch fail to disclose or suggest administering the nutrition composition thereby inducing a pattern of gut barrier maturation in an infant similar to that observed with breast-feeding as required by claim 11.

4. That Brassart fails to disclose the use of a milk-derived oligosaccharide and fails to teach or suggest inducing a pattern of gut barrier maturation in an infant.

5. That the focus of Birch's formulations is on visual acuity and stereoacuity. Applicant asserts that Birch fails to teach inducing a pattern of gut barrier maturation in an infant using a nutritional composition and the skilled artisan would have no reason to arrive at such a method in the absence of hindsight.

6. That Birch fails to disclose the use of a milk-derived oligosaccharide.

7. That the cited references fail to recognize the advantages, unexpected benefits and/or properties of a method in accordance with the present claims.

Applicant's arguments have been fully considered and are not persuasive for the following reasons:

Regarding arguments 1, 4, and 6, contrary to applicant's assertion, Brassart does teach a milk-derived oligosaccharide. In paragraphs 0030-0031, Brassart explicitly states that the nutritional composition can include milk. Milk contains multiple oligosaccharides, all of which are "milk-derived." In addition, Brassart states that the term "milk" refers to both plant and animal milks, such as soy milk. As soy milk contains xylo-oligosaccharides, these can be considered to be "milk-derived." As Brassart explicitly discloses the inclusion of xylo-oligosaccharides in the composition, this is another disclosure of milk-derived oligosaccharides.

Regarding argument 2, simply making such a statement does not provide any actual reasoning or argument to dispute what has already been set forth in the rejection. The rejection as set forth above shows how the claimed composition is rendered obvious.

Regarding arguments 3, 4, 5, and 7, the combination of references clearly teaches administration of the nutritional composition to infants. Whether Brassart and Birch recognized it or not, administering said composition would necessarily result in the induction of a pattern of gut barrier maturation similar to that observed with breast-feeding. They disclose the administration of the same product to the same population as is instantly claimed and it does not appear that it does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure. See *Bristol-Myers Squibb Company v. Ben Venue Laboratories* 58 USPQ2d 1508 (CAFC 2001). It is a general rule that merely discovering and claiming a new benefit of an old process cannot render the process again patentable. *In re Woodruff*, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990). The mechanism of action does not have a bearing on the patentability of the invention if the invention was already known or obvious. Mere recognition of latent properties in the prior art does not render nonobvious an otherwise known invention. *In re Wiseman,* 201 USPQ 658 (CCPA 1979).

In response to applicant's argument that Birch is focused on visual acuity and stereoacuity, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). Birch showed a benefit to adding DHA and/or ARA to infant formulas. This provides a strong reason to include it in the infant formula disclosed by Brassart. The fact that Birch's reasons are different than applicant's does not change the motivation. The reason or

motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant. See, e.g., *In re Kahn*, 441 F.3d 977, 987, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006) (motivation question arises in the context of the general problem confronting the inventor rather than the specific problem solved by the invention); *Cross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc.*, 424 F.3d 1293, 1323, 76 USPQ2d 1662, 1685 (Fed. Cir. 2005) ("One of ordinary skill in the art need not see the identical problem addressed in a prior art reference to be motivated to apply its teachings."); *In re Linter*, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972); *In re Dillon*, 919 F.2d 688, 16 USPQ2d 1897 (Fed. Cir. 1990), cert. denied, 500 U.S. 904 (1991)

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Gangle whose telephone number is (571)272-1181. The examiner can normally be reached on M-F 10-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian J Gangle/
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